

  
IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application of  
Maximilian Angel et al.

Serial No.09/ 767,821

Filed: January 24, 2001

For: Process for preparing water-soluble or water-dispersible  
polyether-containing polymers and the use thereof as coating agents,  
binders and/or film-forming excipients in pharmaceutical dosage  
forms or packaging materials or as additives in cosmetic,  
dermatological or hygienic preparations

#### D E C L A R A T I O N

I, Maximilian Angel, Dr. rer. nat., a citizen of Germany and a  
resident of Bayernstr. 12, 67105 Schifferstadt, Germany, hereby  
declare and say as follows:

I am a fully trained chemist, having studied chemistry at the  
Universities of Erlangen and Bayreuth in the period of from 1975 to  
1982.

I was awarded my PhD in Physical Chemistry at Bayreuth University,  
where in the period of from 1982 to 1985 I worked on colloidal  
systems.

I joined BASF Aktiengesellschaft, located in 67056 Ludwigshafen,  
Germany, in 1986, where I have been engaged in research and  
development in the field of polymers .

I am a co-inventor to Application Serial No.09/767,821;

I have carefully studied the Office Action of September 23, 2003 and  
July 14, 2004, the rejection of the claims under 35 U.S.C. § 103 (a)  
based on the teaching of GB 922,459 in view of the disclosure of Wu  
et al. (US 5,338,814) which documents I have studied as well.

Now, hereby, I want to state the following:

In the Office Actions it was argued that there was motivation to combine the teachings of GB 922,459 and Wu et al. since both teachings are directed to a method of making polymers from monomeric units using free radical solution polymerization. Also, Wu is cited as teaching the advantages of polymerization in the presence of a solution of polyethylene glycol having a MW of about 300, i.e. control of MW of the polymer and not hindering the termination process by viscosity buildup.

However, the control of molecular weight or hindering of viscosity build-up is not a problem to be solved by the presently claimed invention. The problem to be solved is to provide for a safe process for making a graft polymer where vinyl acetate chains are grafted on the backbone of high molecular polyethers.

In GB 922,459 no inert diluent is used. In the polymerization process described in this document the liquid monomer vinyl acetate, polyethylene glycol and the free radical initiator form a solution, but this is not a solution polymerization in the sense the skilled person will understand the term. For the skilled person a solution polymerization is a polymerization where the monomers and the resulting polymer are soluble in an inert diluent (solvent). The important fact is that the skilled person will not look at the process of GB '459 as a process that can be used in a safe and efficient manner on a commercial scale. Since the initial solution, a portion of which is added drop wise to the polymerization vessel by a dropping funnel, contains both the highly reactive vinylacetate and the free radical initiator dibenzoyl peroxide polymerization there is always the risk that premature polymerization will take place in the feed vessel. On a commercial scale such premature polymerization might even cause the eruption of the feed vessel.

As mentioned above, the skilled person would therefore look for an improved method in order avoid such problems.

Wu et al., US 5,338,814 describes a solution polymerization process wherein the water-soluble N-vinylpyrrolidone as a monomer is homopolymerized in the inert diluent (solvent) water and wherein a low molecular polyethylene glycol is used as a chain transfer agent

to control the molecular weight of the growing polyvinyl pyrrolidone chains in order to avoid too high molecular weights and problems associated with increasing viscosity of the reaction medium.

As to the question whether a skilled person would be motivated to combine the teaching of Wu with the teaching of GB '459 in order to solve the problem mentioned above I would like to state as follows.

As stated above the Examiner has taken the position that it was obvious to combine both references because both refer to a solution polymerization in the presence of a free radical initiator.

However, for the skilled person the situation is more complicated. A skilled person generally understands the mechanisms of graft polymerization and the mechanism of homo polymerization as being different. Also, as explained above, GB'459 does not refer to a solution polymerization process in the sense of the solution polymerization taught by Wu. There are additional important differences between the two process taught by the cited prior art.

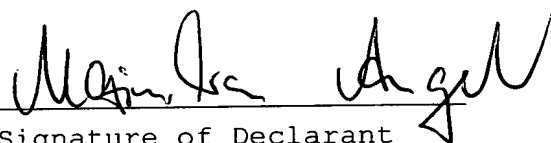
The process taught by Wu relates to a polymerization where the monomer N-vinylpyrrolidone (NVP) is polymerized to give linear homopolymers. N-Vinylpyrrolidone is known to be a monomer not particularly prone to graft polymerization, particularly not in an aqueous solution. As described by Wu, NVP under these conditions will lead to growing linear chains the growth of which must be controlled in order to avoid too high molecular weights. This is achieved by using the low molecular polyethylene glycol as a chain transfer agent that interferes with chain growth.

More so, a skilled person might even assume that a substance that functions as a chain-transfer agent might influence the graft polymerization in the sense that it might interfere with the graft polymerization of the vinyl acetate units onto the high molecular polyethylene glycol backbone.

Thus, it was not obvious to a skilled person to use a low-molecular polyethylene glycol, which according to Wu serves as a chain-transfer agent, as a solvent for the radical former in the process of GB '459 in order to solve the problem described above.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so are made punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed at 67056 Ludwigshafen, Germany, this 30th day of September 2004.

A handwritten signature in cursive script, appearing to read "Maximilian Angel", written over a horizontal line.

Signature of Declarant

Maximilian Angel